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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,910	09/09/2003	Kenichi Chiba	2003946-0056 (ANDI/CIP)	5169
24280 7590 02/23/2007 CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110			EXAMINER OH, TAYLOR V	
			ART UNIT	PAPER NUMBER
			1625	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
31 DAYS		02/23/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/657,910

Applicant(s)

CHIBA ET AL.

Examiner

Taylor Victor Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24,27-31,33,36,38-40,42,43 and 45-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-24,27-31,33,36,38-40,42,43 and 45-66 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/26/06</u> . | 6) <input type="checkbox"/> Other: _____ |

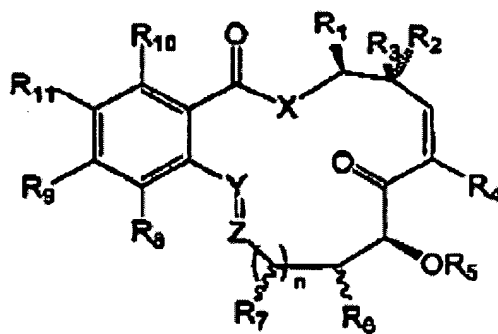
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In view of the amendment filed on 11/29/06, the examiner has decided to withdraw the previous Office Action and to reopen the application with restriction requirement.

Restriction and Election

Restriction to one of the following inventions is required under 35 U.S.C. 121:

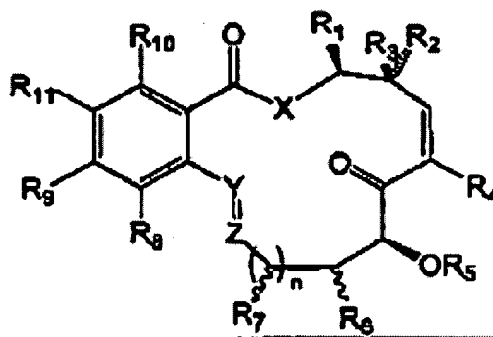
- I. Claims 1-24, 27-31, 33, 36, 38-40, 42-43, 45-63, and 65-66, drawn to a pharmaceutical composition containing the following formula and



wherein X, Y, or Z is equal to

nitrogen., classified in class 540, subclasses 455, 468.

- II. Claims 39-40, 42-43, and 45, drawn to a method for treating rheumatoid arthritis, psoriasis, asthma, sepsis, inflammatory bowel disease atopic dermatitis or Crohn's disease comprising the step of administering to a subject in need thereof a pharmaceutical composition containing the



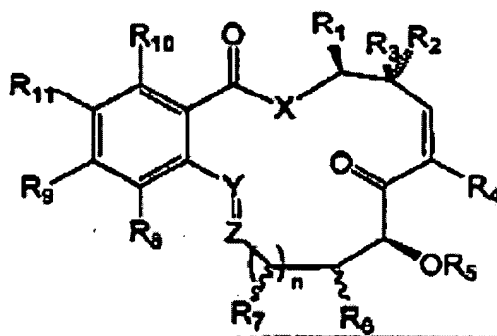
following formula :

wherein

X, Y, or Z each is selected from oxygen, carbon, and nitrogen.

, classified in class 540, various subclasses, class 549, various subclasses.

III Claims 1-24, 27-31, 33, 36, 38-40, 42-43, 45-63, and 65-66, drawn to a pharmaceutical composition containing the following formula

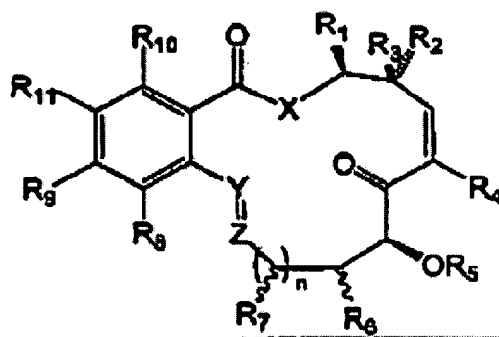


wherein X, Y, or Z is equal to

oxygen., classified in class 549, subclass 267.

IV. Claims 1-24, 27-31, 33, 62-63, and 65-66, drawn to a pharmaceutical composition containing the following formula

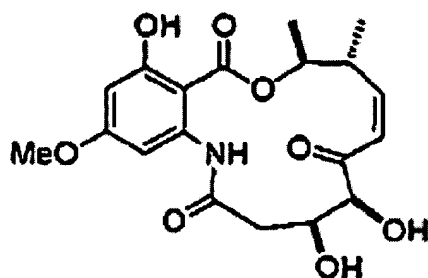
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wherein X is equal to oxygen; Y

and Z are carbon, classified in class 549, subclass 266 .

- V. Claims 61 and 64, drawn to a pharmaceutical composition containing the following formula



, classified in class 540, subclass 450 .

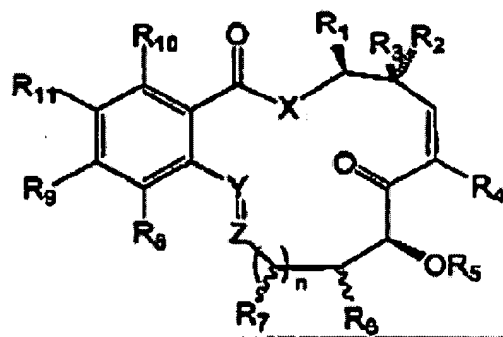
The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

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different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h).

In the instant case, the different inventions, Group I has the following chemical



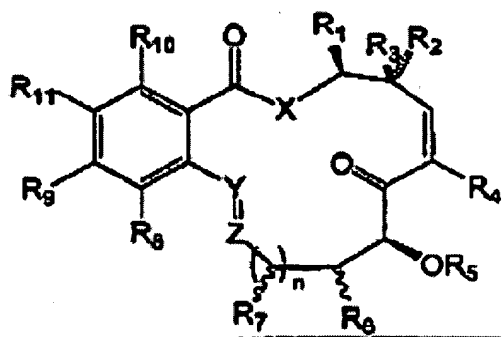
formula

wherein x, y and z are equal to

nitrogen atom, whereas Group II is directed to the method for treating rheumatoid arthritis, psoriasis, asthma, sepsis, inflammatory bowel disease atopic dermatitis or Crohn's disease using the same formula as in Group I. However, Le et al (US 7,138,118) discloses the method of treating rheumatoid arthritis with anti-TNF antibodies unlike the Group II which uses Group I. Thus, the process for using the product as claimed can be practiced with another materially different product.

Therefore, in the instant case, they are two different inventions.

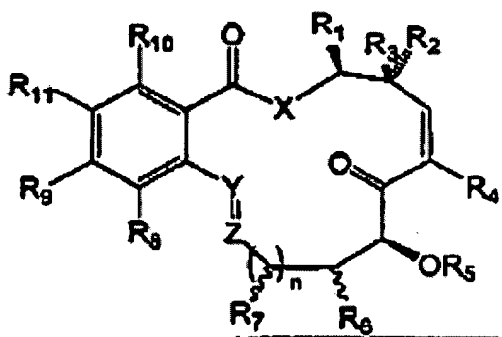
Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions, Group I has the following chemical formula



wherein x, y and z are equal to nitrogen

atom, whereas Group III has the same structure which contains X, Y, or Z being equal to oxygen. Each Group represents a completely different chemical formula with respect to each other, thereby exhibiting different chemical reactions, pharmacological actions, modes of operation, and effects. Therefore, in the instant case, they are two different inventions.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions, Group I has the following chemical formula

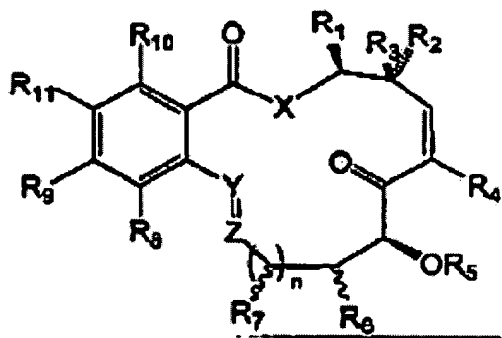


wherein x, y and z are equal to nitrogen

atom, whereas Group IV has the same structure which contains X=O, Y and Z which are equal to carbon. Each Group represents a completely different chemical formula with respect to each other, thereby exhibiting different chemical reactions,

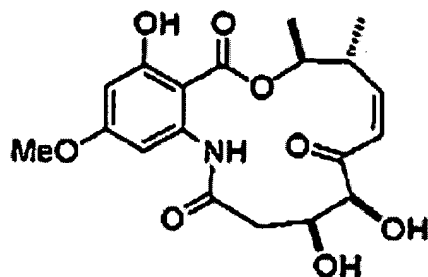
pharmacological actions, modes of operation, and effects. Therefore, in the instant case , they are two different inventions.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions , Group I has the following chemical formula



wherein x, y and z are equal to nitrogen

atom , whereas Group V has the following chemical formula :



Each Group represents a completely different chemical formula with respect to each other, thereby exhibiting different chemical reactions, pharmacological actions, modes of operation, and effects. Therefore, in the instant case , they are two different inventions.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, III, IV, or V, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Taylor Victor Oh, MSD, LAC
Primary Examiner
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2/16/07